**U.S. Department of Justice**
*United States Attorney*
*District of New Jersey*

*PAUL J. FISHMAN*
*United States Attorney*

*R. DAVID WALK, JR.*
*Assistant United States Attorney*

*CAMDEN FEDERAL BUILDING & U.S. COURTHOUSE* 856.757.5164
*401 Market Street, 4th Floor* Fax: 856.968.4917
*Post Office Box 2098*
*Camden New Jersey 08101-2098*

May 25, 2016

Cr. 16-316 (ES)

A. Ross Pearlson, Esq.
Chiesa Shahinian & Giantomasi PC
One Boland Drive
West Orange, NJ 07052

Re: Plea Agreement with Pharmaceutical Innovations, Inc.

Dear Mr. Pearlson:

This letter sets forth the plea agreement between your client, Pharmaceutical Innovations, Inc. ("Pharmaceutical Innovations"), and the United States Attorney for the District of New Jersey ("this Office"). The government's offer to enter into this plea agreement will expire on June 10, 2016 if it is not accepted in writing by that date.

## Charge

Conditioned on the understandings specified below, this Office will accept a guilty plea from Pharmaceutical Innovations to a two-count Information, which charges the defendant with two counts of introducing into interstate commerce adulterated medical devices, in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 351(a). If Pharmaceutical Innovations enters a guilty plea and is sentenced on this charge, and otherwise fully complies with all of the terms of this agreement, this Office will not initiate any further criminal charges against Pharmaceutical Innovations for introducing into interstate commerce devices contaminated with microorganisms for the period beginning in or about January 2011, through in or about December 2012. However, in the event that a guilty plea in this matter is not entered for any reason or the judgment of conviction entered as a result of this guilty plea does not remain in full force and effect, Pharmaceutical Innovations agrees that any dismissed charges and any other charges that are not time-barred by the applicable statute of limitations on the date this agreement is signed by Pharmaceutical Innovations may be commenced against it.

notwithstanding the expiration of the limitations period after Pharmaceutical Innovations signs the agreement.

The Office expressly reserves the right to prosecute any individual, including but not limited to present and former officers, directors, employees, and agents of Pharmaceutical Innovations, in connection with the conduct encompassed by this plea agreement or known to the Office.

Sentencing

Each violation of 21 U.S.C. § 331(a) to which Pharmaceutical Innovations agrees to plead guilty carries a statutory maximum term of probation of five years and a statutory maximum fine equal to the greatest of: (1) $200,000; (2) twice the gross amount of any pecuniary gain that any persons derived from the offense; or (3) twice the gross amount of any pecuniary loss sustained by any victims of the offense. See 18 U.S.C. §§ 3561(c)(2), 3571(c)(5), (d). Fines imposed by the sentencing judge may be subject to the payment of interest.

The sentence to be imposed upon Pharmaceutical Innovations is within the sole discretion of the sentencing judge, subject to the provisions of the Sentencing Reform Act, 18 U.S.C. §§ 3551-3742, and the sentencing judge's consideration of the United States Sentencing Guidelines. The United States Sentencing Guidelines are advisory, not mandatory. The sentencing judge may impose any reasonable sentence up to and including the statutory maximum term of probation and the maximum statutory fine. This Office cannot and does not make any representation or promise as to what guideline range may be found by the sentencing judge, or as to what sentence Pharmaceutical Innovations ultimately will receive.

Further, in addition to imposing any other penalty on Pharmaceutical Innovations, the sentencing judge: (1) will order Pharmaceutical Innovations to pay an assessment of $125 per count, pursuant to 18 U.S.C. § 3013, which assessment must be paid by the date of sentencing; (2) must order Pharmaceutical Innovations to pay restitution pursuant to 18 U.S.C. § 3563(b)(2); and (3) may order Pharmaceutical Innovations to give notice to any victims of its offense pursuant to 18 U.S.C. § 3555.

In addition, Pharmaceutical Innovations agrees to make full restitution for all losses resulting from the offense of conviction or from the scheme, conspiracy, or pattern of criminal activity underlying that offense.

Rights of This Office Regarding Sentencing

Except as otherwise provided in this agreement, this Office reserves its right to take any position with respect to the appropriate sentence to be imposed on Pharmaceutical Innovations by the sentencing judge, to correct any misstatements relating to the sentencing proceedings, and to provide the sentencing judge and the United States Probation Office all law and information relevant to sentencing, favorable or otherwise. In addition, this Office may inform the sentencing judge and the United States Probation Office of: (1) this agreement; and (2) the full nature and extent of Pharmaceutical Innovations' activities and relevant conduct with respect to this case.

Stipulations

This Office and Pharmaceutical Innovations agree to stipulate at sentencing to the statements set forth in the attached Schedule A, which hereby is made a part of this plea agreement. This agreement to stipulate, however, cannot and does not bind the sentencing judge, who may make independent factual findings and may reject any or all of the stipulations entered into by the parties. To the extent that the parties do not stipulate to a particular fact or legal conclusion, each reserves the right to argue the existence of and the effect of any such fact or conclusion upon the sentence. Moreover, this agreement to stipulate on the part of this Office is based on the information and evidence that this Office possesses as of the date of this agreement. Thus, if this Office obtains or receives additional evidence or information prior to sentencing that it determines to be credible and to be materially in conflict with any stipulation in the attached Schedule A, this Office shall not be bound by any such stipulation. A determination that any stipulation is not binding shall not release either this Office or Pharmaceutical Innovations from any other portion of this agreement, including any other stipulation. If the sentencing court rejects a stipulation, both parties reserve the right to argue on appeal or at post-sentencing proceedings that the sentencing court was within its discretion and authority to do so. These stipulations do not restrict this Office's right to respond to questions from the Court and to correct misinformation that has been provided to the Court.

Waiver of Appeal and Post-Sentencing Rights

As set forth in Schedule A, this Office and Pharmaceutical Innovations waive certain rights to file an appeal, collateral attack, writ, or motion after sentencing, including but not limited to an appeal under 18 U.S.C. § 3742 or a motion under 28 U.S.C. § 2255.

Forfeiture

As part of its acceptance of responsibility and pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461(c), Pharmaceutical Innovations agrees to forfeit all right, title, and interest in lots 090111 and 040212 of Other-Sonic ultrasound gel. Pharmaceutical Innovations agrees that as a result of its acts or omissions, a substantial portion of the forfeitable property, that is the devices deemed adulterated, are no longer available for forfeiture as the devices cannot be located or have been transferred, sold or deposited with a third party, or otherwise disposed of, within the meaning of federal law. See 21 U.S.C. § 853(p); 28 U.S.C. § 2461(c). As a result, Pharmaceutical Innovations agrees to the entry of a forfeiture money judgment on the date of the guilty plea in the amount of $50,000.00 (the "Forfeiture Money Judgment").

Payment of the Forfeiture Money Judgment shall be made by certified or bank check payable to the United States Marshals Service, with the criminal docket number noted on the face of the check. Pharmaceutical Innovations shall cause said check to be hand delivered to the Asset Forfeiture and Money Laundering Unit, United States Attorney's Office, District of New Jersey, 970 Broad Street, Newark, New Jersey 07102.

If the Forfeiture Money Judgment is not paid on or before the date Pharmaceutical Innovations enters its plea of guilty pursuant to this agreement, interest shall accrue on any unpaid portion thereof at the judgment rate of interest from that date. Furthermore, if Pharmaceutical Innovations fails to pay any portion of the Forfeiture Money Judgment on or before the date of its guilty plea, Pharmaceutical Innovations consents to the forfeiture of any other property, including substitute assets, in full or partial satisfaction of the money judgment, and remains responsible for the payment of any deficiency until the Forfeiture Money Judgment is paid in full.

Pharmaceutical Innovations also agrees to consent to the entry of a Consent Judgment and Order of Forfeiture for the Forfeiture Money Judgment, and any further orders that may be necessary to enforce the Forfeiture Money Judgment, and waives the requirements of Rules 32.2 and 43(a) of the Federal Rules of Criminal Procedure regarding notice of the forfeiture in the charging instrument, announcement of the forfeiture at sentencing, and incorporation of the forfeiture in the judgment. Pursuant to Rule 32.2(b)(4) of the Federal Rules of Criminal Procedure, the defendant consents to the entry of a Consent Judgment of Forfeiture that will be final as to the Forfeiture Money Judgment prior to the defendant's sentencing. Pharmaceutical Innovations understands that the imposition of the Forfeiture Money Judgment is part of the sentence that may be imposed in this case and waives any failure by the court to advise it of this pursuant to Rule 11(b)(1)(J) of the Federal Rules of Criminal Procedure at the guilty plea proceeding.

It is further understood that any forfeiture of Pharmaceutical Innovations' assets shall not be treated as satisfaction of any fine, restitution, cost of imprisonment, or any other penalty the Court may impose upon it in addition to forfeiture. Pharmaceutical Innovations hereby waives any and all claims that the forfeiture constitutes an excessive fine and agrees that the forfeiture does not violate the Eighth Amendment.

It is further understood that the Office will recommend to the Attorney General that any forfeited money or property be remitted or restored to eligible victims of the offense, pursuant to 18 U.S.C. § 982(b)(1), 21 U.S.C. § 853(i), 28 C.F.R. Pt. 9, and other applicable law, it being understood that this Office has authority only to recommend such relief and that the final decision of whether to grant relief rests with the Department of Justice, which will make its decision in accordance with applicable law.

Notice

To facilitate notice to potential victims, within 10 days after Pharmaceutical Innovations enters its guilty plea, Pharmaceutical Innovations shall provide to the United States Probation Office and this Office a list of the names and addresses of all recipients of lots 090111 and 040212, whether or not the recipients returned any portion of those lots to Pharmaceutical Innovations. The list of recipients shall include all distributors, customers, and health care providers that were sent or received lots 090111 and 040212 and all individual patients whom Pharmaceutical Innovations has any reason to believe were exposed to lots 090111 and 040212.

Other Provisions

This agreement is limited to the United States Attorney's Office for the District of New Jersey and cannot bind other federal, state, or local authorities. However, this Office will bring this agreement to the attention of other prosecuting offices, if requested to do so.

This agreement was reached without regard to any civil or administrative matters that may be pending or commenced in the future against Pharmaceutical Innovations. This agreement does not prohibit the United States, any agency thereof (including the Internal Revenue Service) or any third party from initiating or prosecuting any civil or administrative proceeding against Pharmaceutical Innovations.

No provision of this agreement shall preclude Pharmaceutical Innovations from pursuing in an appropriate forum, when permitted by law, an appeal, collateral attack, writ, or motion claiming that Pharmaceutical Innovations received constitutionally ineffective assistance of counsel.

Pharmaceutical Innovations agrees that it is authorized to enter into this agreement, that it has authorized the undersigned corporate representatives to take this action, and that all corporate formalities for such authorization have been observed. Pharmaceutical Innovations further agrees that the plea of guilty will be entered by Charles Buchalter, Pharmaceutical Innovations' current President and Chief Executive Officer and authorized corporate representative, and that Charles Buchalter is authorized to enter a plea of guilty on Pharmaceutical Innovations' behalf. Charles Buchalter is entering the plea as Pharmaceutical Innovations' current authorized corporate representative, as he was appointed Pharmaceutical Innovations' President and Chief Executive Officer in September 2014, and Pharmaceutical Innovations represents that prior to September 2014, Charles Buchalter had no involvement with the operations of Pharmaceutical Innovations. By entering this guilty plea, Pharmaceutical Innovations hereby waives all objections to the form of the charging documents and admits that it is in fact guilty of the offenses set forth in the Information.

No Other Promises

This agreement constitutes the plea agreement between Pharmaceutical Innovations and this Office and supersedes any previous agreements between them. No additional promises, agreements, or conditions have been made or will be made unless set forth in writing and signed by the parties.

Very truly yours,

PAUL J. FISHMAN
United States Attorney

By: R. David Walk, Jr.
Assistant United States Attorney

APPROVED:

Jacob T. Elberg
Chief, Health Care & Government Fraud Unit

I am the authorized corporate representative for Pharmaceutical Innovations. I have received this letter from A. Ross Pearlson, Esq., who is the attorney for Pharmaceutical Innovations. I have read the letter. Mr. Pearlson and I have discussed it and all of its provisions, including those addressing the charge, sentencing, stipulations, and waiver. I understand this letter fully. On behalf of and with the express authorization of Pharmaceutical Innovations, I hereby accept its terms and conditions and acknowledge that it constitutes the plea agreement between the parties. I understand that no additional promises, agreements, or conditions have been made or will be made unless set forth in writing and signed by the parties. Pharmaceutical Innovations wants to plead guilty pursuant to this plea agreement.

AGREED AND ACCEPTED:

Charles Buchalter (signature) Date: 6/9/2016

Charles Buchalter
As Authorized Corporate Representative for
Pharmaceutical Innovations, Inc.

I am counsel for Pharmaceutical Innovations. I have discussed with my client this plea agreement and all of its provisions, including those addressing the charge, sentencing, stipulations, and waiver. Further, I have fully advised the authorized corporate representative of Pharmaceutical Innovations' rights regarding this plea agreement and all of its provisions, including those addressing the charge, sentencing, stipulations, and waiver. My client, Pharmaceutical Innovations, understands this plea agreement fully and wants to plead guilty pursuant to it.

A. Ross Pearlson (signature) Date: 6/9/2016

A. Ross Pearlson, Esq.

Plea Agreement With Pharmaceutical Innovations

Schedule A

1. This Office and Pharmaceutical Innovations recognize that the United States Sentencing Guidelines are not binding upon the Court. This Office and Pharmaceutical Innovations nevertheless agree to the stipulations set forth herein.

2. The version of the United States Sentencing Guidelines effective November 1, 2015, applies in this case. The applicable guideline is U.S.S.G. § 8A1.1.

3. Pharmaceutical Innovations agrees that in response to subpoenas served on June 5, 2012, and August 21, 2012, it failed to produce over 20 test results showing that its ultrasound gel products tested positive for the presence of microorganisms. Pharmaceutical Innovation subsequently produced those positive test results in response to a grand jury subpoena served on March 4, 2014.

4. The Office and Pharmaceutical Innovations agree to recommend that the Court impose a fine of $50,000 and agree that such a fine is appropriate. See U.S.S.G. § 8C2.10.

5. The Office and Pharmaceutical Innovations agree to recommend that the Court impose a term of probation of two years and agree that this term of probation is necessary and reasonable. See U.S.S.G. §§ 8D1.1(a)(1), (2), (6), and (8), 8D1.2.

6. The Office and Pharmaceutical Innovations agree to recommend that the Court order as a special condition of probation that Pharmaceutical Innovations comply with the Consent Decree of Condemnation and Permanent Injunction between the United States and Pharmaceutical Innovations in United States v. All Articles of Other-Sonic Generic Ultrasound Transmission Gel, Civ. No. 12-02264-ES-JAD (D.N.J.) and United States v. Pharmaceutical Innovations, Inc., Civ. No. 14-06139-ES-JAD (D.N.J.) and agree that this condition is necessary and reasonably related to the nature and circumstances of the offense and the history and characteristics of Pharmaceutical Innovations. See U.S.S.G. § 8D1.3(c).

7. If the sentencing court accepts a stipulation set forth above, both parties waive the right to file an appeal, collateral attack, writ, or motion claiming that the sentencing court erred in doing so. Otherwise, both parties reserve the right to file, oppose, or take any position in any appeal, collateral attack, or proceeding involving post-sentencing motions or writs.